



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

**WARNING LETTER**  
**VIA EXPRESS**

P.T. Eka Wira Asia  
Managing Director  
J1 Haji Zainal Arifin 128 B-C  
Medan 20112, Indonesia

MAR 3 1999

Re: Entry # GL5-0600406-5

Dear Sir or Madam:

Based on a Food and Drug Administration (FDA) analysis of the above identified shipment, as well as analyses of previous shipments, we have reason to believe that there may be deficiencies in the method by which you manufacture, inspect, test, package, store, or ship patient examination gloves. Patient examination gloves are medical devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

You received notification from FDA that your device shipments had been found to be violative for defects by FDA analysis, placing you on level 1 and level 2 detentions. You were previously notified on January 14, 1999, by FDA of the requirements of the Quality System (QS) regulation and the potential for problems if these requirements are not given serious attention. It is your responsibility to ensure adherence to each requirement of the Act and its implementing regulations. The letter also discussed the importance of complying with the QS Regulation, and informed you that failure to comply could result in increased levels of detention.

The current FDA analysis, as well as previous analyses, document continuing violations. Your patient examination gloves are, therefore, adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packaging, storage or installation are not in conformance with current Good Manufacturing Practice (GMP) requirements as set forth in the Quality System Regulation, specified in Title 21, Code of Federal Regulations (21 CFR, Part 820).

Because your firm has now been on detention three times in the last 24 months, your firm is now considered to be on level 3 detention. At level 3 detention, analytical evidence alone may not be sufficient to show that the gloves have been manufactured to meet minimum quality standards. Further evidence, such as an inspection by FDA (or by a qualified third party, in some instances) to assess conformance with the QS regulation may be needed for a firm to be removed from level 3 detention. As a first step, you should undertake a

comprehensive review of your manufacturing procedures and practices to assure conformance with the requirements of the QS regulation. You are responsible for determining the cause of the violations identified by FDA. If the causes are determined to be systems problems, you must initiate permanent corrective actions and you must respond to FDA as described below.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts.

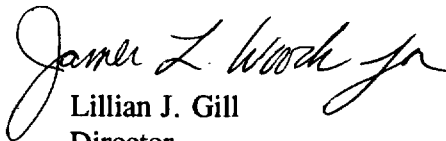
Given the serious nature of the violations of the Act, all patient examination gloves shipped by P.T. Eka Wira Asia, located in Medan, Indonesia, may be detained without physical examination upon entry into the United States until the violations are corrected.

After performing a comprehensive review of your manufacturing procedures, it will be necessary for you to provide a written response to the charges in this Warning Letter. Please notify this office, in writing, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to the U.S. Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement II, General Hospital Devices Branch, HFZ-333, at the letterhead address, to the attention of Carolyn B. Niebauer, Chief.

If you have more specific questions about the contents of this letter, please feel free to contact Rebecca Keenan, at the address indicated above, or at (301) 594-4618, or you may FAX her at (301) 594-4638.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lillian J. Gill".

Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices and Radiological Health